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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,014	SU ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10, 12, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/22/08 wherein claims 1, 9, and 12 were amended and claims 2, 11, and 14 were amended.

Note: Claims 1, 3-10, 12, and 13 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 8/22/08 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejection (Written Description)

The rejection of claims 1, 3-10, 12, and 13 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED-IN-PART. Specifically, the rejection is WITHDRAWN as it relates to the phrase 'Morinda citrifolia juice is present in an amount of 2.31 percent by volume'. The claims were amended to set forth that it is a concentration of 2.31%, not a volume of 2.31%. However, the rejection as it relates to the claims lacking written description because the term 'inhibits/inhibition' COX-1 and COX-2 is not describe in such a way to convey to the Reader that Applicant had possession of the invention at the time of filing is MAINTAINED.

Applicant asserts that the claims do not indicate exactly the amounts of inhibition or that complete inhibition would be accomplished. Instead, it is Applicant's position that the claims are drawn to a method of selectively inhibiting COX-2 relative to COX-1 by administering a specified concentration of a Morinda citrifolia juice product.

Applicant refers to Example 1 for support that a concentration of 2.31% inhibited COX-1 by 20% and COX-2 by almost 60% while a concentration of 10% Morinda citrifolia juice inhibited COX-1 approximately 83% and inhibited COX-2 approximately 84%.

Applicant's response confirms that the term 'inhibit/inhibition' is not described in such a manner to clearly convey what is being claimed. For example, at a concentration of 2.31%, Applicant's Example 1 indicates a specific amount of inhibition occurred (COX-1 was inhibited by 20% and COx-2 was inhibited by 58%). Thus, a response that the claims do not indicate exactly the amounts of inhibition or that complete inhibition would be accomplished is confusing. In addition, it is noted that while the claims are directed to administering a specific concentration of Morinda citrifolia juice, the claims do not indicated any particular amount of inhibition. Hence, according to Applicant's response, even though a concentration of 2.31% is administered, there may be no, complete, little, or may be a great deal of inhibition. In other words, based on the amended claims and Applicant's response it is possible that no inhibition can occur. Also, if one reviews claim 6, the phrase 'dose of Morinda citrifolia inhibits the production of COX-2 related prostaglandins that cause pain and inflammation and inhibits to a lesser extent, the production of COX-1 related prostaglandins' may be interpreted as there is no COX-2 production, but some COX-1 production. In addition, the phrase may be interpreted as one has both COX-2 and COX-1 production. However, based on the independent claims wherein a concentration of 2.31% is administered, it is possible to have complete or not inhibition; however, the specification sets forth that you must have a specific amount of inhibition at a

concentration of 2.31%. Thus, the 112, first paragraph, rejection (the claims lack written description) is deemed proper.

112 First Paragraph Rejection (Enablement Rejection)

The enablement rejection is WITHDRAWN because Applicant has amended the claims to replace the term 'volume' with 'concentration' as set forth in the specification.

112 Second Paragraph Rejections

Notes: It should be noted that in Applicant's response filed 8/22/08, Applicant did not respond to the Examiner's 112, second paragraph, rejections. However, some of the rejections were WITHDRAWN because of Applicant's amendment to the claims.

The rejection of claims 1, 3-10, 12, and 13 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention are MAINTAINED-IN-PART for the reasons set forth below.

The rejection of claims 1, 3-10, 12, and 13 as being ambiguous because it is disclosed that the Morinda citrifolia is a juice, but in some of the dependent claim, the material is a food product is MAINTAINED for reasons of record in the office action mailed 5/23/08.

The rejection of claims 9, 10, 12, and 13 as being unclear whether Applicant is treating both the pain and inflammation is WITHDRAWN because the claims were amended to overcome the rejection.

The rejection of claims 1 and 3-8, and newly amended claims 9, 10, 12, and 13, as being ambiguous because it is unclear how one is interpreting the term 'inhibition' is MAINTAINED for reasons of record in the office mailed 5/23/08.

103 Rejection

The 103 rejection is WITHDRAWN because Applicant has amended the claims to subject matter disclosed in the provisional application filed 12/05/2000. Thus, Applicant is now entitled to that particular date. As a result, the Jensen et al document is no longer prior art since its earliest date is 11/2/2001.

Notes: It should be noted that Applicant's comments about the Gidlund document (US Patent No. 6,436,449) are not persuasive for the following reasons. Applicant asserts that Gidlund has a priority date depending from a provisional filed March 2, 2000 while the instant Applicant is entitled to a date of December 5, 2000. First, March 2, 2000 is prior to December 5, 2000; thus, the reference is prior art against the instant invention. Secondly, Applicant references an affidavit attached to the response filed 8/22/08. However, review of the application does not indicate that an affidavit was filed with Applicant's response.

NEW GROUNDS OF REJECTION

112 First Paragraph Rejection (New Matter)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-10, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claims contain new matter. Specifically, the amended claims are directed to a concentration of 2.31%. The specification discloses that at a concentration of 2.31%, the Morinda citrifolia juice administered resulted in COX-1 inhibition by 20% and COx-2 inhibition by 58%. However, the pending claims read on a range of possible inhibition ranging from no inhibition to complete inhibition. If Applicant is in disagreement with the Examiner, Applicant is respectfully requested to point to page(s) and line(s) where support may be found for the pending claims.

112 First Paragraph Rejection (Scope of Enablement)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-10, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for COX-1 inhibition by 20% and COx-2 inhibition by 58% when a concentration of 2.31% of Morinda citrifolia juice is administered to a subject, does not reasonably provide enablement for complete inhibition or any other inhibition of COX-1 and/or COX-2, other than COX-1 inhibition by 20% and COx-2 inhibition by 58%, when a concentration of 2.31% of Morinda citrifolia

juice is administered. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to methods of selectively inhibiting COX-2 relative to COX-1 by administering a concentration of 2.31% of Morinda citrifolia juice to a subject.

(2) State of the prior art

The state of the prior art is that it is difficult to selectively inhibit COX-2 and/or COX-1 because cyclooxygenases are involved in various biochemical processes that affect various parts of the body. For example, the cyclooxygenases are associated with various conditions (i.e., all kinds of pain and inflammation) that affect the body. The pain and inflammation may be that associated with cancer since according to Hallahan (US Patent No. 6,159,443, column 22, lines 9-20), inflammatory condition include those

that are immune and non-immune related. Possible conditions include rheumatism, psoriasis, diabetic retinopathy, neovascular glaucoma, atherosclerotic plaques and osteoporosis, as well as conditions such as cancer. A condition such as cancer remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, October 15, 1999, pp. 531-537) that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types in order to maximize efficacy and minimize toxicity. The classification of cancer has been based primarily on morphological appearance of the tumor and that of tumors with similar histopathological appearance may follow significantly different clinical courses and have different responses to therapy (see Golub et al., Science, October 15, 1999, pp. 531-537). As a result, there is no absolute predictability of which tumors are treatable, even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the knowledge in the art would hinder one of ordinary skill in the art from accepting any therapeutic regimen as being acceptable for all tumor/cancer treatments. Additionally, for example, infection is a process that can take place in virtually any part of the body. Thus, there is a vast range of infectious diseases that may occur based on the various biochemical pathways.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of any amount of inhibition, if

any at all, that patients who have been administered a concentration 2.31% of Morinda citrifolia will experience. Thus, the assumption that the administering of Morinda citrifolia will inhibit COX-1 and/or COX-2 completely or in amounts other than COX-1 inhibition by 20% and COX-2 inhibition by 58% is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the specific amount of inhibition, if any, that occurs using varying amounts and concentration of the processed juice.

(4) Level of predictability in the art

The art pertaining to the inhibiting COX-2 and/or COX-1 is highly unpredictable. Determining the various concentrations that affect COX-2 and/COX-1 associated diseases/conditions requires various experimental procedures and without guidance that is applicable to all concentrations of processed Morinda citrifolia juice, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

There is no evidence of record which would enable the skilled artisan in determining the amount of inhibition, if any, of COX-2 and/or COX-1. While the specification does disclose Example 1 wherein when a concentration of 2.31% of Morinda citrifolia is administered, one gets COX-1 inhibition by 20% and COx-2 inhibition by 58%. Hence, there is no enablement for all possible inhibition levels when a concentration of 2.31% of Morinda citrifolia juice is administered.

(6) Existence of working examples

The instant invention encompasses a vast number of possible inhibition levels. Applicant's limited working examples do not enable the public to prepare and use such a numerous amount Morinda citrifolia mixtures.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible inhibition levels known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation in determining the various inhibition levels. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

COMMENTS/NOTES

7. It should be noted that Applicant has amended the claims to contain information disclosed in the provisional application filed 12/5/2000. Specifically, the claims have been amended to a concentration of 2.31%, not an amount of 2.31% by volume which was not disclosed in the provisional application. Thus, the claims have been amended such that Applicant is now entitled to the 12/5/2000 date.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

December 7, 2008